UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC Defendants.	12 Civ. 8115 (TPG)
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and BARR LABORATORIES, INC. Defendant.	12 Civ. 8060 (TPG)
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. IMPAX LABORATORIES, INC. and THORX LABORATORIES, INC. Defendants.	12 Civ. 8317 (TPG)

(captions continued on following pages)

ENDO PHARMACEUTICALS INC., Plaintiff, v. ACTAVIS INC. and ACTAVIS SOUTH ATLANTIC LLC, Defendants.	:	12 Civ. 8985 (TPG)
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. IMPAX LABORATORIES, INC., Defendants.	:	13 Civ. 435 (TPG)
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. ACTAVIS INC, ACTAVIS SOUTH ATLANTIC LLC, and WATSON PHARMACEUTICALS, INC., Defendants.	:	13 Civ. 436 (TPG)

ENDO PHARMACEUTICALS INC.,	:	
Plaintiff,	:	
v.	:	13 Civ. 3288 (TPG)
ROXANE LABORATORIES, INC.,	:	
Defendant.	:	
ENDO PHARMACEUTICALS INC.,	:	
Plaintiff,	:	
v.	:	13 Civ. 4343 (TPG) 13 Civ. 8597 (TPG)
SUN PHARMACEUTICAL INDUSTRIES, LTD.	:	
Defendant.	:	

Omnibus Opinion

Defendants Actavis, Inc. and Actavis South Atlantic LLC (together, "Actavis") and Roxane Laboratories, Inc. (collectively, "Moving Defendants") have filed motions under Federal Rules of Civil Procedure 52(b), 59(e), and 60(a) to alter, amend, or correct the judgment; motions and requests to strike and unseal; requests to alter the complaint per Rule 15(b); a request to stay this matter pending appeal; and a request to schedule a damages trial and order discovery relating to damages. Certain other defendants have filed similar motions. This flurry of filings followed a five-week, consolidated bench trial and a 154-page opinion of August 14, 2015 in which the court found, in relevant part, that the Moving Defendants infringed the '122 and '216 patents of Endo Pharmaceuticals, Inc.

For the following reasons, the court declines to alter the effective dates of Moving Defendants' Abbreviated New Drug Applications ("ANDAs") but exercises its equitable power to enjoin Moving Defendants. In addition, the court denies Actavis's request for a stay and Endo's request to schedule a damages trial and order discovery.

Background

Shortly after this court held, in relevant part, that Moving Defendants' generic products infringed Endo's '122 and '216 patents, *Endo Pharms, Inc. v. Roxane Labs., Inc.*, No. 13-cv-3288, ECF No. 194 at 55–58, 68 n.10, Moving Defendants filed separately to alter or amend the court's judgment per Rule 59(e) or, in the alternative, for a stay pending appeal, *Endo Pharms. v. Actavis Inc.*, No.

12-cv-8985, ECF Nos. 109–12 (Actavis briefing); *Endo Pharms. v. Roxane Labs., Inc.*, No. 13-cv-3288, ECF Nos. 202–03 (Roxane briefing). Endo filed its own motions to amend and correct the judgment under Rules 52(b) and 60(a). *Endo Pharms. v. Teva Pharms. Inc.*, No 12-cv-8060, ECF No. 240; No. 12-cv-8985, ECF Nos. 113–15, 124. The parties then exchanged oppositions, replies, requests to strike, and, in Endo's case with respect to Actavis's Rule 59(e) motion, an unauthorized surreply under seal. On February 16, 2016, Actavis moved to strike Endo's surreply and the declaration attached thereto, and to have those documents filed on the public docket. No. 12-cv-8985, ECF Nos. 150–51. These matters are now fully briefed before the court.

Discussion

A. Motions to Alter or Amend

The court will first consider Endo's motion to alter or amend the judgment under Rule 52(b), No. 12-cv-8060, ECF Nos. 240–41, and Moving Defendants' separate motions to alter or amend the judgment under Rule 59(e), No. 12-cv-8985, ECF Nos. 109–12 (Actavis briefing); No. 13-cv-3288, ECF Nos. 202–03 (Roxane briefing).

Rules 52(b) and 59(e) give the court discretion to alter or amend its findings and judgment. We review Rule 59(e) and Rule 52(b) motions under the same standard. *Soberman v. Groff Studios Corp.*, 2000 WL 1253211, at *1 n.1 (S.D.N.Y. Sept. 5, 2000). A district court may grant a Rule 52(b) or Rule 59(e) motion to correct manifest errors of law or fact at trial, *Muyet v. United States*, No. 01-cv-9371, 2005 WL 1337369, at *2 (S.D.N.Y. June 6, 2005) (citation

omitted), or, in some limited situations, in the face of newly discovered evidence. *Bazuaye v. United States*, No. 09-cv-8288, 2011 WL 1201696, at *1 (S.D.N.Y. 2011) (citation omitted).

Despite their similarities, Rule 52(b) and Rule 59(e) motions have distinct applications. Rule 52(b) provides a method to dispute underlying facts that resulted in faulty factual findings or conclusions of law based on those facts. Rule 59(e) provides for a broad request for reconsideration of the judgment itself. Under Rule 59(e), this court may alter or amend the judgment only "to correct a clear error of law or prevent manifest injustice." *Schwartz v. Liberty Mut. Ins. Co.*, 539 F.3d 135, 153 (2d Cir. 2008) (citation omitted). Where a party fails to dispute facts in the record, a motion under Rule 52(b) is inappropriate. *Muyet*, No. 01-cv-9371, 2005 WL 1337369, at *2.

Endo's arguments in its Rule 52(b) motion are legal in nature. It asks the court to address the Supreme Court's decision in *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006). And although Endo's Rule 52(b) motion appends proposed additional findings of fact in addition to conclusions of law for the court to consider, those facts are all in service of a purely legal finding under *eBay*. Thus, Endo's September 21, 2015 motion must be construed as a motion under Rule 59(e). *See United States v. Local 1804-1, Int'l Longshoremen's Ass'n*, 831 F. Supp. 167, 169 (S.D.N.Y. 1993) (holding that a Rule 52(b) motion is an inappropriate way to advance new legal theories, relitigate old issues, or rehear judgments on the merits).

Here, the two core issues to be decided under Rule 59(e) are: (1) whether the effective date of Moving Defendants' ANDAs should be altered, per 35 U.S.C. § 271(e)(4)(A); and (2) whether the court should issue an injunction against Moving Defendants. For the reasons set forth in detail below, the court will alter and amend its order and judgment as to both issues.

a. *Remedies Under 35 U.S.C. § 271(e)(4)(A)*

Before the court directly addresses the Rule 59(e) motions, the court will first give greater context to the § 271 statutory scheme and to the pharmaceutical patent process, more generally.

When a drug pioneer creates and sufficiently tests a new product, the pioneer submits a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA"). A patent for that new drug can issue before or after the FDA approves the NDA. Once the FDA approves an NDA, however, the pioneer enjoys a period of regulatory exclusivity.

The Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act created § 505(j) (codified at 21 U.S.C. § 355(j)), which established the ANDA-approval process. That process permits generic versions of previously-approved innovator drugs to be approved without submission of a full NDA. The ANDA process can save drug companies time and money because it allows the ANDA to refer to a previously approved NDA and to rely upon the FDA's finding of safety and effectiveness for that drug product.

While Congress made it easier for generic drug companies to access the market through the ANDA process, Congress also imposed limitations on generic

companies. For certain types of drugs, Hatch-Waxman established a period of marketing exclusivity during which time generic drug companies cannot submit an ANDA. *See* 21 U.S.C. § 355(j)(5)(F). As a mechanism of enforcement before the generic drug company begins marketing its product, Congress enabled patent holders of pioneer drugs to establish in court that there has been an act of infringement. *See* 35 U.S.C. § 271(e)(2); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 668 (1990) (explaining that the Hatch-Waxman "scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement").

Section 271(e)(2)(A) thus makes it "an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]" If a fact-finder has found that a defendant has infringed a patent under 35 U.S.C. § 271(e)(2), the statute provides that "the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." § 271(e)(4)(A). The court may also grant additional remedies, including a permanent injunction or the award of monetary damages. § 271(e)(4)(B)–(C).

In motions before this court, Actavis argues that the effective dates of its ANDAs should not have been changed under § 271(e)(4)(A), and Roxane seeks alteration or amendment of the judgment to reflect that it did not infringe the '122 and '216 patents under § 271(e)(2). The court addresses these requests in

tandem because they ask essentially the same question: whether Moving defendants infringed the '122 and '216 patents under § 271(e)(2) such that Endo is entitled to relief under § 271(e)(4)(A).[1]

The statutory scheme created by the Hatch-Waxman Act and § 271(e)(2) does not permit Endo to obtain relief against Moving Defendants under § 271(e)(4)(A). This is so because the '122 and '216 patents had not issued at the time Moving Defendants filed their ANDAs. As alluded to above, § 271(e)(2)(A) provides a patentee with a cause of action for patent infringement based solely upon the filing of an ANDA containing a certification implicating a patentee's rights. And as noted above, § 271(e)(2) makes it an act of infringement to submit an ANDA under § 355(j) for "a drug claimed in a patent or the use of which is claimed in a patent." Notably, the subject of the sentence is "a patent," not a provisional patent application or a patent-pending. Moreover, the statute's use of the past-tense phrase "claimed in a patent" suggests that the ANDA must relate to a drug that has *already* been claimed in a patent. In other words, the statute requires the prospective ANDA to relate to a patent that had already been issued at the time of the ANDA's submission. *Accord Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc.*, 821 F. Supp. 2d 681, 697 (D. N.J. 2011), *aff'd sub nom. Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, 748 F.3d 1354 (Fed. Cir. 2014) (finding that infringement under 35 U.S.C. § 271(a)–(c) does not trigger § 271(e)(4)).

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[1] As the parties should be aware, the court's analysis here applies only to those ANDAs submitted by Moving Defendants prior to the issue of Endo's patents.

The Federal Circuit's decision in *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366 (Fed. Cir. 2006), is not to the contrary. In that case, Impax submitted an ANDA based on a patent that had issued years before. However, Impax received FDA approval of its ANDA before any relevant patent was listed in the public listing of patents, often referred to as the Orange Book. *Id.* at 1372–73. Impax became aware of a relevant patent while preparing its ANDA. *Id.* A dispute arose between Impax and the prospective patent-holder, and, before trial, Impax and the patentee ultimately entered into a stipulation whereby Impax conceded that its ANDA product infringed various claims of the patentee's patent. *Id.* The parties proceeded to litigate and try the case on other grounds. Going forward, however, neither the district court nor the Federal Circuit actually addressed whether an infringement action under § 271(e)(2) can lie where a patent was issued after the filing or approval of an ANDA. It is therefore improper to cite *Impax* for the proposition that a patent-holder can maintain an action under § 271(e)(2) where the patent issued after the filing of an ANDA.

Endo's argument in opposition would impose infringement liability on an ANDA filer if a patent were to issue *at any time* after the ANDA is filed. This argument has no basis in the text and it overlooks a primary purpose of the Hatch-Waxman Act, which is to facilitate "the early resolution of patent disputes between generic and pioneering drug companies by providing that the mere act of filing . . . [an] ANDA constitutes an act of patent infringement." *Caraco Pharm. Labs., Ltd. v. Forest Labs.*, Inc., 527 F.3d 1278, 1283 (Fed. Cir. 2008) (citing 35 U.S.C. § 271(e)(2)). The statute allows a court to find an existing case or

controversy even though the generic drug has not yet been marketed or sold. *Id.* at 1283–85. Congress's creation of this early-stage cause of action is what makes a suit under § 271(e)(2) "artificial." *See Eli Lilly*, 496 U.S. at 678. But this early-stage adjudication is useless if, at the time the generic drug company submits its ANDA, no patent has issued.

The proposed statutory scheme would also delay or even prevent ANDA-filers from enjoying finality with respect to litigation risk. Downstream holders of partial patents could sue ANDA-filers, even though those downstream partial patent holders were never conceived of at the time that the generic company submitted its ANDA. This uncertainty conflicts with other purposes of the statute, which include "facilitat[ing] the development of generic versions of listed drugs," *Caraco*, 527 F.3d at 1282, and "incentiviz[ing] ANDA filers to challenge the validity of listed patents or design around those patents as early as possible," *id.*

Ultimately, there is no textual support for the notion that the statute was drafted to provide post-ANDA patent holders with a "gotcha" cause of action based on the filing of the ANDA when the patent issues years after. Rather, the simplest and most cogent interpretation holds that it is an act of infringement to submit an ANDA for a drug claimed in a patent or the use of which is claimed in a patent *when that patent is issued at the time a company submits its ANDA.*

The '122 and '216 patents issued years after Moving Defendants filed the relevant ANDAs. Accordingly, Endo cannot be awarded relief under § 271(e)(4)(A)

because it was not eligible for infringement liability under § 271(e)(2).[2] The court's findings of fact and law as well as the judgement will be amended and altered accordingly.[3]

b. *Injunctive Relief*

While the court has found that Endo is not eligible for the relief set forth in § 271(e)(4), the court has the general equitable power to issue an injunction upon the finding of patent infringement under § 271(a)–(c). *See, e.g.*, *eBay*, 547 U.S. 388.

Before the court can enjoin Moving Defendants, Endo must demonstrate that such relief would be fair and equitable pursuant to the Supreme Court's analysis in *eBay*. In that case, the Court recognized that a patent owner prevailing on the merits in a patent infringement suit is not automatically entitled to an injunction. *eBay*, 547 U.S. at 390. Rather, courts apply traditional equitable principles to determine: (1) whether the patentee would be irreparably harmed without an injunction; (2) whether the patentee has an adequate remedy at law; (3) whether the balance of hardships favors an injunction; and (4) whether granting the injunction is in the public interest. *Id.* at 391. The court will apply these considerations to the facts of this case.

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[2] For this reason, requests to alter the complaint per Federal Rule of Civil Procedure 15(b) are denied.

[3] It should be noted that this does not alter the court's original holding that relief under 35 U.S.C. § 271(e) is appropriate as to all defendants other than Roxane and Actavis. Those other defendants were found to infringe under § 271(e)(2)(A) and thus the court alters the effective dates of the relevant ANDAs, in compliance with § 271(e)(4)(A). The court will determine whether an injunction is appropriate under § 271(e)(4)(B) after considering the parties' briefing on the issue. *See infra* n.4.

i. Irreparable Harm

A patentee must show that it would suffer irreparable harm from infringement if the court were to decline to issue an injunction against the patent infringer. This requires proof that a "causal nexus relates the alleged harm to the alleged infringement." *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012). The purpose of the causal nexus requirement is to establish the link between the infringement and the harm, to ensure that there is "some connection" between the harm alleged and the infringing acts. *Apple, Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1364 (Fed. Cir. 2013). Thus, a plaintiff can demonstrate irreparable harm "by showing that it will likely suffer an injury and, separately, satisfy the nexus requirement by showing that this injury is causally linked to the infringement." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 652 (Fed. Cir. 2015).

Where a plaintiff and an infringer directly compete in the same market, an injunction may be warranted to protect the plaintiff from irreparable harm. *See Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013); *see also* Douglas Ellis et al., *The Economic Implications (and Uncertainties) of Obtaining Permanent Injunctive Relief After* Ebay v. MercExchange, 17 Fed. Circuit B.J. 437, 442 & nn.39–40 (2008). Competition is logically tied to injury, since directly competitive companies are most likely to be rivals for market share, sales, customers, profits, business opportunities, goodwill, and brand power.

When a patentee alleges it suffered irreparable harm stemming from lost sales solely due to a competitor's infringement, a finding that the competitor's

infringing features drive consumer demand for its products satisfies the causal nexus inquiry. *Id.* at 641. But this rule is neither categorical nor is it mechanically applied; the four-factor *eBay* analysis exists because it may well be impossible if for the patentee to proffer affirmative evidence showing direct causation. *See id.* Whether a patentee has made a causal showing is, of course, a discretionary determination. *Id.*

While injunctive relief is designed to address future harms, past harm is relevant as an indicator of the future. *Id.* at 652 (citing *United States v. Oregon State Med. Soc.*, 343 U.S. 326, 333 (1952) (Jackson, J.)). Accordingly, a patentee may rely on past irreparable harm as well as prospective harm to support its request for an injunction. *See eBay*, 547 U.S. at 391 (noting that a patentee must demonstrate that "it *has suffered* an irreparable injury") (emphasis added); *see also i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 861–62 (Fed. Cir. 2010) (finding that evidence of past irreparable harm was sufficient to support an injunction and citing cases); *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975 (Fed. Cir. 1996) (discussing the relevance of past harm where the danger of future infringement exists).

A patentee's willingness to license does not necessarily evince a lack of irreparable harm or preclude an injunction, *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323, 1339 (Fed. Cir. 2005), *vacated and remanded on other grounds*, 547 U.S. 388 (2006), nor does the existence of other competitors in the market, *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1381 (Fed. Cir. 2005).

In this case, Endo, Roxane, and Actavis are direct competitors in the oxymorphone market. No. 12-cv-8985, ECF No. 121 at 12–16. The fact that Endo's non-crushable tablet is not automatically substituted at the pharmacy for Moving Defendants' crushable generics does not militate a different conclusion. It is not as if the formula of Endo's tablet is "but a small component" of the tablet that Actavis seeks to continue producing. *See eBay*, 547 U.S. at 396–97 (Kennedy, J. concurring). Rather, the court found that Moving Defendants' entire products infringed on Endo's entire product. This infringement is not vitiated simply because the drugs differ in crush resistance.

Endo convincingly argued at trial that to allow additional generics, such as Roxane's, into the market would cause injury to Endo. *See* Trial Tr. 854:22, 859:24–860:2, 888:21–889:1. In addition, Endo persuasively reasoned that Actavis's presence in the market has caused and will continue to cause Endo to lose market share, profits, and goodwill. No. 12-cv-8985, ECF No. 121 at 19–22. And contrary to Actavis's view that Endo would be harmed only by *additional* generics entering the market, Endo has provided and specifically described the harms that the sale of Actavis's product has caused and would continue to cause. *Id.* It has substantiated those claims by citing to sales and market data, and has identified the market share, revenue, and customers that Endo has lost to Actavis. Specifically, Endo has lost eleven percent of its market share to Actavis, alone. *Id.* at 19. It was also forced to cut its pain sales force by one quarter, to reduce its promotional expenses, and to alter its research and development strategies. *Id.* at 20–22.

Endo's stated harms are no less valid simply because some are past harms. Actavis launched its infringing product "at-risk" in the face of a potential injunction after trial. The at-risk launch has already encroached on Endo's bottom line. In this way, the at-risk launch portends more harm to Endo if the court declines to grant Endo an injunction. The court finds that those harms are more than financial, but are reputational, organizational, and administrative. These intangible harms are irreparable, and there is also no reason to believe that Moving Defendants will stop infringing, or that the irreparable harms resulting from its infringement will otherwise cease, absent an injunction. *See Reebok Int'l, Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1557 (Fed. Cir. 1994) (recognizing that "future infringement . . . may have market effects never fully compensable in money"); *Telequip Corp. v. Change Exch.*, No. 01-cv-1748, 2006 WL 2385425, at *2 (N.D.N.Y. Aug. 15, 2006).

Endo's past license to Impax pursuant to a litigation settlement does not negate the harms Endo has experienced and would suffer in the future from Moving Defendants' infringement. Endo's actual and potential losses of revenue, market share, and customers to Moving Defendants pose a true threat and require legal redress by this court.

ii. Adequacy of Legal Remedy

Certain competitive harms can be offset by money damages or other remedies at law. In this way, the first two *eBay* elements are closely tied. Yet legal remedies may not be able to adequately compensate for harms that are difficult to quantify. *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336,

1344 (Fed. Cir. 2013) ("Irreparable injury encompasses different types of losses that are often difficult to quantify, including lost sales and erosion of reputation and brand distinction.").

Endo has demonstrated that it has suffered and would continue to suffer difficult-to-quantify harms resulting from Moving Defendants' infringement. The infringement has caused Endo to lose forty percent of its share of the oxymorphone market, Trial Tr. 819, eleven percent of which is directly attributable to Actavis alone, Lortie Decl. ¶ 8. These losses have compounded problems in ways that would be difficult to quantify. Namely, Endo claims that it has had to lay off twenty-five percent of its relevant sales force. Trial Tr. 826–27; DTX-2501 ¶¶ 16, 42–52; Lortie Decl. ¶¶ 6, 11–14. These layoffs may damage Endo's reputation in its market segment and have also made the company less attractive to potential new hires. Trial Tr. 847–48, 853–54; DTX-2501 ¶¶ 42–52; Lortie Decl. ¶¶ 11–14. Endo's decline has caused it to decelerate its investment in research and development. Trial Tr. 857–59; Lortie Decl. ¶¶ 11–14. These are precisely the types of irreparable harm that an injunction is designed to remedy. Simple remuneration would not adequately address these irreparable harms.

iii. Balance of Hardships

Endo has argued that it will suffer hardship if the court does not enjoin Moving Defendants from infringing Endo's patent. With respect to Actavis, Endo preemptively argues that any of Actavis's purported harms are of its own making when it launched at-risk. No. 12-cv-8985, ECF No. 121 at 22–23. Actavis, on

the other hand, has not argued that it would suffer hardship. Rather, Actavis expounds on the ways in which *Endo* has supposedly failed to show hardship. *See id.* ECF No. 111 at 4–12. Actavis also asserts that "there is no evidence that enjoining Actavis's product will materially benefit . . . Endo." *Id.* at 11. These assertions are not the same as a supported statement that Actavis would suffer hardship. The court's task is to weigh one party's potential hardship against the other's, and Actavis's silence as to its own hardship is significant.

Roxane's reasoning suffers from a similar defect. Roxane makes no affirmative arguments as to why Endo does not deserve an injunction. Rather, it argues incorrectly that Endo cannot be awarded an injunction if it neither pled nor won its infringement suit on § 271(e)(2) grounds. No. 13-cv-3288, ECF No. 202, at 2–3; No. 13-cv-3288, ECF No. 216, at 1–3. In addition, Roxane has not described the hardship it would suffer in the event the court enjoined its future infringement of the '122 and '216 patents.

The court has found above that Endo would suffer irreparable harm from Moving Defendants' continued infringement. The scale tips in favor of Endo where Moving Defendants have not shown that they would suffer hardship.

iv. Public Interest

The court likewise finds that "the public interest would not be disserved by a permanent injunction." *eBay*, 547 U.S. at 391. Endo is the rightful patent owner, and the Federal Circuit "has long acknowledged the importance of the patent system in encouraging innovation. Indeed, the 'encouragement of investment-based risk is the fundamental purpose of the patent grant, and is

based directly on the right to exclude.'" *SanofiSynthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (quoting *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985)).

Endo has also provided sound reasons why the public interest would affirmatively favor an injunction. Crushable tablets, like the ones marketed by Moving Defendants, are more easily abused by patients. To the extent that the injunction also serves the interest of making a heavily-abused opioid less susceptible to abuse, the public interest is served. *See* PTX-937 (opining that reducing availability of "non-tamper-resistant" opioids serves the public interest); Trial Tr. at 830, 845, 2807. It should also be noted that there is also a public interest in protecting and promoting patent rights. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). The public interest factor weighs in favor of enjoining Moving Defendants.

In sum, all four *eBay* factors support enjoining Moving Defendants with respect to the infringing claims on the '122 and '216 patents.

B. Motion to Stay

The court has found that the *eBay* factors favor granting an injunction against Moving Defendants. Yet Actavis seeks a stay of this injunction pending appeal. No. 12-cv-8985, ECF No. 111 at 16. In deciding whether to suspend its injunction pending appeal, this court must consider: "(1) whether [Actavis] has made a strong showing that it is likely to succeed on the merits; (2) whether [Actavis] will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure [Endo]; and (4) where the public interest lies."

Standard Havens Prods. v. Gencor Indus., 897 F.2d 511, 513 (Fed. Cir. 1990) (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)); *see also United States v. Eastern Airlines, Inc.*, 923 F.2d 241, 244 (2d Cir. 1991). When assessing those factors, the court follows a flexible approach and will require a lesser showing of harm if Actavis is likely to succeed on the merits on appeal and will require a more substantial showing of harm if the likelihood of success is low. *See Standard Havens*, 897 F.2d at 513–15. Considering the facts in this action in light of the standard set forth above, this court concludes that a stay is not warranted.

As to the first factor, Actavis tepidly states that on appeal it is likely to succeed or has "at least" a "substantial case." No. 12-cv-8985, ECF No. 111 at 16. The only reason Actavis provides for this assertion is based on the court's failure to recite the *eBay* factors in its August opinion. *Id.* The court has now applied the *eBay* factors, and those factors weigh against Actavis. Actavis offers no other substantial reasons as to this first factor.

On the second factor, Actavis argues that it would suffer irreparable harm absent a stay of the injunction. The stay would supposedly harm its goodwill and reputation in the industry because customers will be forced to undergo the difficult process of changing suppliers. *Id.* at 17–18. But these were the hazards Actavis accepted when it launched at-risk. It knew there was a patent infringement action against it and thus knew or should have known that there was a possibility—however remote—that it may someday be barred from

marketing the product in question. Actavis's anticipated harms are, thus, of its own making.

As to the third factor, Actavis next argues that Endo would not be harmed by such a stay. *Id.* at 18. But Endo convincingly argued that it has and would continue to suffer irreparable injury absent an injunction. The court agrees with that argument, and it equally agrees that a stay of the injunction would impose on Endo many of the same harms that a blanket injunction denial would. Moreover, recent product development by Endo indicates that Endo would particularly benefit from finality of this action and from the injunction at this time. Endo wishes to reinvigorate its marketing and development of Opana® ER and has taken steps to do so. No. 13-cv-8987, ECF No. 147. Delaying Endo its due remedy would impose further harm on it.

Finally, Actavis contends that the public interest favors a stay pending appeal because the first three factors above weigh in its favor. No. 12-cv-8985, ECF No. 111 at 18. With this circular reasoning, the court disagrees. While it is true that an injunction is a drastic remedy, an injunction can serve the ends of justice where it is warranted. The court holds that an injunction is warranted without a stay, whole or partial.

C. Motion to Correct

Endo has also moved to correct the judgment per Rule 60(a), which allows a court to "correct a clerical mistake or a mistake arising from oversight or omission whenever one is found in a judgment, order, or other part of the record." No. 12-cv-8985, ECF Nos. 113–15; Fed R. Civ. P. 60(a). Rule 60(a) further

provides that, "after an appeal has been docketed in the appellate court and while it is pending, such a mistake may be corrected only with the appellate court's leave." This matter was appealed to the Federal Circuit but the Federal Circuit deactivated those appeals on November 10, 2015. *See Endo Pharms. Inc. v. Actavis Inc.*, No. 16-1025 (Fed. Cir. Nov. 10, 2015). Therefore, no appeals are currently pending and this court need not seek leave of the Federal Circuit to correct clerical mistakes under Rule 60(a).

Endo's motion is opposed by Actavis, which is joined in opposition by defendants Teva Pharmaceuticals USA, Inc. and Barr Laboratories, Inc. *See Endo Pharms. Inc. v. Actavis Inc.*, No. 13-cv-436, ECF No. 155 (Actavis's opposition); No. 12-cv-8060, ECF No. 239 (Teva and Barr's memorandum). The opposition argues that Endo's requested amendments are outside the scope of Rule 60(b) because they are unnecessary and because the existing language is already clear. The court has found that certain of Endo's corrections are well taken because they help to clarify the court's intent at the time of issuing the judgment and do not rely on new evidence or reasoning. Accordingly, undisputed clerical errors and certain disputed amendments under Rule 60(b) will be made in a judgment to be docketed under a separate ECF number.[4]

[4] Aside from Moving Defendants, the parties have not weighed in on how the four *eBay* factors favor or disfavor the imposition of an injunction in each particular case. The court will issue a separate Order inviting all parties aside from Moving Defendants to submit briefing on this topic. The final amended judgment in this case will be issued after that briefing is complete.

D. Motions & Requests to Strike

The court will now turn to the parties' various motions and requests to strike.

a. *Actavis's Motion to Strike Endo's Surreply & the Harlow Declaration*

Actavis has moved to strike as untimely and unseal Endo's surreply and the related Harlow declaration, No. 12-cv-8985, ECF No. 149, which respond in further opposition to Actavis's Rule 59(e) motion to alter or amend the judgment, No. 12-cv-8985, ECF Nos. 109–12. The court will strike the surreply as untimely and to remove it from seal.

It is beyond dispute that the decision to permit a litigant to submit a surreply is a matter left to the court's discretion, *Kapiti v. Kelly*, No. 07-cv-3782, 2008 WL 754686, at *1 n.1 (S.D.N.Y. Mar. 12, 2008), as is the decision to strike a party's filing, *Aurora Loan Servs., Inc., v. Posner, Posner & Assocs., P.C.*, 513 F. Supp. 2d 18, 19 (S.D.N.Y. 2007). Here, Endo neither sought nor received permission from the court to file a surreply to Actavis's motion to alter or amend the judgment. This contravenes the general principle that supplementary filings require leave of the court. Moreover, the filing ignores this court's individual rules, which specifically require leave to be sought if a party wishes to be heard outside the ordinary course. Individual Practices of Judge Thomas P. Griesa 2(C) (updated Nov. 18, 2014). Accordingly, this court exercises its discretion to grant Actavis's motion to strike Endo's unauthorized surreply and the Harlow declaration.

Actavis also asks the court to unseal Endo's now-stricken filing. Generally, there is a presumption that the public should be able to access all documents filed in this court. *SEC v. TheStreet.com*, 273 F.3d 222, 231 (2d Cir. 2001). Federal Rule of Civil Procedure 26(c) affords the court some discretion to decide whether and to what extent this general rule applies. In particular, a court may issue an order "requiring that a trade secret or other confidential research, development, or commercial information . . . be revealed only in a specified way." Fed. R. Civ. P. 26(c)(1)(g). This court did precisely that when it entered a protective order that permitted the parties to file certain papers under seal consistent with this court's individual rules. No. 12-cv-8985, ECF No. 31 at 1–2. That order requires parties seeking to file materials under seal to "move for permission to file the materials under seal contemporaneously." Individual Practices of Judge Thomas P. Griesa 3(B) (last updated Jan. 16, 2016). In such a motion, the party seeking protection bears the burden of establishing good cause for the issuance and continuation of a protective order. *Gambale v. Deutsche Bank AG*, 377 F.3d 133, 142 (2d Cir. 2004). In assessing whether good cause exists, courts in the Second Circuit look to whether the documents sought to be sealed are judicial documents to which the public has a presumptive right of access, the weight of that presumption, and the balance of competing considerations against that presumption. *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 119 (2d Cir. 2006); *see also United States v. Amodeo*, 71 F.3d 1044, 1048–52 (2d Cir. 1995).

In this matter, Endo has not provided specific information as to why its filings must be sealed. Rather, Endo stated flatly and without substantive explanation that the material discussed in its brief was "simply confidential." No. 12-cv-8985, ECF No. 153 at 4. "But implicit in the notion of 'confidential business information' is something beyond the mere fact that the particular datum has not previously been made available to the public." *Salomon Smith Barney, Inc. v. HBO & Co.*, No. 98-cv-8721, 2001 WL 225040, at *3 (S.D.N.Y. Mar. 7, 2001). Endo has fallen short of making the required showing to keep its materials confidential.

Even if Endo's brief indeed contains confidential information meriting seal, Endo has not explained why it failed to seek permission to file under seal, nor has it justified why it declined to undertake the less restrictive approach of redacting the confidential parts of its brief and declaration. Accordingly, Endo may seek leave to redact confidential parts of its brief and declaration within ten days of the filing of this opinion. If no such request is made within ten days, the Clerk of Court is ordered unseal the brief and declaration and file them on the public docket.

b. *The Lortie Declaration*

Actavis contends that Endo improperly submitted the declaration of Brian Lortie, who previously submitted a declaration in support of Endo's preliminary injunction motion in 2013 and who also testified before this court in the 2015 trial. No. 12-cv-8985, ECF No. 126, at 2–3. Lortie's new declaration

accompanies Endo's opposition to Actavis's Rule 59(e) motion to alter or amend the judgment. No. 12-cv-8985, ECF Nos. 109–11.

Actavis argues that Lortie's new declaration is improper because it constitutes new evidence that Endo failed to offer at trial. In its defense, Endo simply asserts in a footnote that Lortie's declaration responds to Actavis's submission of the declaration of Andrew S. Boyer, No. 12-cv-8985, ECF No. 121 at 13 n.4, though Endo admits that Boyer's declaration is "principally directed" toward opposing Actavis's request for a stay of the injunction pending appeal. Endo adds that courts "frequently rely on" declarations accompanying post-trial motions.

However procedurally irregular the addition of the Lortie declaration may be, Actavis has not moved to strike it. Therefore, with respect to the Lortie declaration, there is no pending application or request for the court to decide. Therefore, the court has considered Lortie's declaration, particularly those parts that are corroborated by evidence and testimony given at trial.

It is also worth noting that Actavis has not argued that it has been deprived of a meaningful opportunity to respond to Endo's new post-trial declaration, nor has Actavis asked the court for leave to further brief any new evidence Lortie raises in his declaration.

c. *Roxane's Request to Strike Endo's Opposition as Untimely*

Roxane has asked the court to strike as untimely Endo's opposition to Roxane's Rule 59(e) motion. *Endo Pharms. Inc. v. Roxane Labs.*, Inc., No. 13-cv-3288, ECF No. 216 at 6. Endo countered by letter stating that its motion was

timely because its electronically-filed motion was entitled to a three-day extension. Letter from Brian M. Goldberg, Oct. 6, 2015, No. 13-cv-3288, ECF No. 218. Given this three-day allowance, for which Roxane neglected to account, Endo's opposition was timely. Roxane's request to strike Endo's opposition as untimely is denied.

d. *Timeliness of Endo's Rule 52(b) Motion*

Endo made a motion to alter or amend this court's findings and conclusions under Federal Rule of Civil Procedure 52(b), and Actavis has requested that the court strike this motion as untimely. No. 12-cv-8985, ECF No. 134, at 3–7. Rule 52(b) provides that, within 28 days after the entry of judgment, a party may ask the court to amend its findings and make additional findings, and the court may amend its judgment accordingly. A "judgment" is distinguishable from other pronouncements of the court, and the Rules specify that "[e]very judgment must be set out in a separate document." Fed. R. Civ. P. 58. The separate document rule is designed to reduce uncertainty for the litigants with respect to the date of final disposition of a case. *Axel Johnson Inc. v. Arthur Andersen & Co.*, 6 F.3d 78, 84 (2d Cir. 1993). The court entered judgment in this matter on August 24, 2016. Endo therefore had until September 21, 2016, to file a Rule 52(b) motion, and indeed Endo filed its motion on that day. The motion was timely.

E. Request for Damages Trial & Discovery

Endo also requests that this court schedule a damages trial and order Actavis to respond to certain outstanding discovery demands. The court declines

to do so at this time. Endo already consented to bifurcate liability from damages issues in this case. Appeals from this court's decision on liability will inevitably follow, and any decision from the Federal Circuit will surely affect the damages phase of this case. It is prudent to await the resolution of any appeal before scheduling a damages trial or conducting discovery related to damages. *See generally* 28 U.S.C. § 1292(c)(2) (providing that an appeal may be taken from a determination of liability without the district court being required to adjudicate damages); *Robert Bosch, LLC v. Pylon Mfg. Corp.*, 719 F.3d 1305 (Fed. Cir. 2013) (same). Endo's request is denied.

Conclusions

For the reasons set forth above, the court declines to alter the effective dates of Moving Defendants' ANDAs under 35 U.S.C. § 271(e)(4)(A) but enjoins Moving Defendants from making or selling their generic products prior to the expiration of the '122 and '216 patents. The court declines to enter a stay pending appeal and declines to schedule a damages trial. Finally, the court will file a corrected judgment under a separate docket number.

This omnibus opinion resolves all open items for the following docket numbers: 12-cv-8060, 12-cv-8115, 12-cv-8317, 12-cv-8985, 13-cv-0435, 13-cv-0436, 13-cv-3288, 13-cv-4343, and 13-cv-8597.

SO ORDERED.

Dated: New York, New York
April 29, 2016

Thomas P. Griesa
U.S. District Judge